REMARKS

Previous Claim Rejections

Applicant respectfully submits that cancellation of claims 10-22 renders all the pending rejections moot, and that the substituted claims 28-71 are patentable.

Discussion of the Claimed Invention in Light of the References Cited in the November 29, 2002 Office Action

Unlike the vector cardiogram approach presented, for example, in the already cited Karlsson reference that treats an electrocardiogram (EKG) signal as a single time evolving event viewed in projection, the multidimensional (*i.e.*, in multivariate space) approach of the presently claimed invention recognizes that cardiac electrical activation (plus non-cardiac, distal signal sources) is not a single event and that multiple EKG leads in geometrically different locations differ in their sensitivity to local and distal signal sources. Classic 12-lead EKGs including local chest leads are not adequately reproduced by the vector method, and, in fact, the vector method has fallen out of favor due to the loss of important diagnostic information in vectorcardiography.

The presently claimed invention, which isolates magneto effects, uses different sensitivities to local and distal signal sources in its derivation of output data. In particular, the artifacts from aorta and vena cava in or near a magnetic field, which result in magneto effects called "pseudo-T wave", are not distinguishable in general from normal T wave and obscure it in projection or vector methods, unless they happen to have perpendicular projections. They are, however, distinctive in the multi-dimensional approach of the presently claimed invention, in part because local cardiac signal sources differ among different local chest leads distinctly from the impact of distal signal sources in which the progressive differences with small vertical and horizontal displacements is smaller and follow a distinctive pattern of comparison when viewed as concurrent multi-dimensional data.

The presently claimed invention provides a method of concurrent multi-dimensional data collection that distinguishes local from distal signal sources that are not

readily distinguishable when summed into a single net signal. It is the multi-dimensional signal characterization that captures the key distinguishing data that enables substantial elimination of the non-cardiac signals. An ability of the presently claimed invention is the ability to eliminate magneto effects of blood movement in aorta and veins when in or near a magnetic field, and the effects of magnetic field gradients that produce voltages similar to EKG signals when magnetization is modulated as for MRI.

Karlsson addresses conventional (one-dimensional temporal voltages) EKG data with no distinction between local and distal (non-cardiac) signal sources, and no ability to address false T waves and false R waves from magneto effects on great vessels or effects of gradients such as occur during magnetic resonance imaging (MRI). Karlsson refers to conventional 12-lead EKG configurations, but that is quite different from the multi-dimensional data collection as in the presently claimed invention, and Karlsson does not address computer isolation of local from distal signal sources. Karlsson focuses on analysis and display applicable to one-dimensional data (voltage vs time), which inherently cannot distinguish local vs. distal sources of signal unless they happen to reliably have different temporal patterns (not the case for the false/pseudo T wave or narrow-spike false R waves observed during MRI). The multi-dimensional processing of the presently claimed invention distinguishes local vs. distal contributions to signal independent of temporal pattern, and thus enables substantial elimination of distal and global signal sources. Karlsson does teach application of temporal filters to eliminate artifacts. Temporal filters eliminate certain temporal patterns regardless of whether they were generated from the heart locally, or from a distal source such as the great vessels, or globally from the body under the influence of magnetic field gradient changes.

McEachern addresses the fading of trace signals on old cathode ray displays and is therefore not relevant to the present claimed invention.

Snell describes telemetry from a pacemaker to report the sequence of conventional (one-dimensional) temporal events from the point of view of an internal sensor in the pacemaker, and offers conventional surface EKG signals also for comparison. Snell does not teach or suggest generating special signals for legacy systems to identify R-wave occurrences.
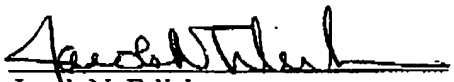
For at least the above noted reasons, Applicant respectfully submits that claims 28-71 are patentable and in a condition for allowance. Favorable consideration and allowance are earnestly solicited. Should there be any questions after reviewing this paper, the examiner is invited to contact the undersigned at 617-854-4000.

Respectfully submitted,

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Appendix A: Claims

1-9. (Canceled, previously non-elected)

10-22. (Canceled, previously elected)

23-27. (Canceled, previously non-elected)

28. (New) Method of multidimensional cardiac monitoring, comprising the steps of:

positioning a plurality of physiologic signal sensors at geometrically distinct positions on a body relative to a heart, each one of the sensors coupled to one of a plurality of signal channels via one or more leads;

acquiring via the signal sensors multidimensional physiologic (MP) signals from the heart; and

deriving from the acquired MP signals output data, said output data representative of cardiac electrical activation events and including signal information not encompassed by any single signal channel.

29. (New) The method of claim 28, wherein the deriving step further comprises the step of:

extracting from the acquired MP signals undesirable signals attributable to distal, global and external signal sources through comparison of the undesirable signals acquired on two or more of the signal channels so as to isolate a local cardiac signal.

30. (New) The method of claim 29, further comprising the step of:

externally generating on one or more of the signal channels one or more signals containing information relative to external undesirable signal sources.

31. (New) The method of claim 29, wherein:

the undesirable signals comprise respiratory baseline artifacts; and

the extracting step further comprises the steps of

analyzing the MP signals through a low frequency curve fit or

filter to determine the respiratory baseline artifacts, and

subtracting the respiratory baseline artifacts from the MP signals.

32.   (New) The method of claim 28, wherein:

each signal channel is coupled to a sensor by a plurality of electrically conducting leads of similar trajectory not all of which are in electrical contact with the sensor, such that a common spurious signal is acquired in each lead attributable to signal sources external to the body; and

the deriving step further comprises the step of extracting the common signal from the acquired MP signals.

33.   (New) The method of claim 32, wherein the plurality of electrically conducting leads are twisted.

34.   (New) The method claim 28, wherein the deriving step further comprises the step of:

comparing the acquired MP signals to stored data to determine what aspects of the acquired MP signals are useful for generation of the output data.

35.   (New) The method of claim 34, wherein the stored data comprise a plurality of signal sources such that the comparing step distinguishes local, distal, global or external signal contributions to the MP signals.

36.   (New) The method of claim 34, wherein the stored data comprise electrocardiogram data obtained in the absence of one or more undesirable signals.

37.   (New) The method of claim 28, further comprising the step of:

outputting the data output, the data output including an indicator relative to the duration of one or more cardiac cycles so as to permit corrections for variation in a cardiac filling period.

38.   (New) The method of claim 28, wherein the deriving step further comprises the steps of:

determining if the MP signals fit constraints reflective of the expected temporal evolution of the MP signals and defining acceptable variations relating to one or more of the following: noise spikes, scaled or corrupted signal channels, aberrant heart beats or otherwise unreliable data; and

editing the MP signals to fit the constraints if said MP signals do not fit so as to obtain descriptive values reflective of desired signal features.

39.   (New) The method of claim 38, wherein the deriving step further comprises the step of:

fitting feature template components determinative of output data information content to the descriptive values so as to generate the output data.

40.   (New) The method of claim 38, wherein the constraints include one or more of the following: previously acquired MP signals from the same heart, expected cardiac cycle averages and variance values, empiric data, data previously acquired by scanning prior ECG's, data acquired from one or more other patients indicating expected co-variant ranges, patterns and parameters, or data collected on gradient effects or magneto effects of medical equipment.

41.   (New) The method of claim 38, wherein the desired signal features include one or more of the following: P-wave, R-wave, ST-segment, T-wave, respiratory phase from baseline artifact, and wave morphologies.

42.   (New) The method of claim 28, wherein the cardiac electrical activation events include one or more of P wave, R wave, QRS wave, ST segment deviation, T wave, respiratory cycle baseline artifact, beat-to-beat and other temporal wave morphologies.

43.   (New) The method of claim 28, further comprising the step of:

computing from the output data running average values for repetitive cardiac electrical events over a pre-selected time period.

44. (New) The method of claim 28, further comprising the steps of:

comparing the output data to historical cardiac information to determine if the heart filling interval is uniform or non-uniform; and

setting indicators if the heart filling interval is non-uniform.

45. (New) The method of claim 28, further comprising the step of:

generating from the output data a synthetic ECG signal including indications of cardiac electrical activity.

46. (New) The method of claim 45, wherein the synthetic ECG signal includes a superimposed R-wave spike and ST segment deviations that have been corrected for baseline artifacts and magneto effects.

47. (New) The method of claim 45, further comprising the step of:

providing a means within the synthetic ECG signal permitting measurement of ST segment deviations even in the presence of magnetic disturbances.

48. (New) The method of claim 45, further comprising the step of:

pre-defining morphological rules to which the synthetic ECG must conform.

49. (New) The method of claim 45, further comprising the step of:

offsetting one or more segments of the synthetic ECG signal to permit identification of the presence of or changes in ischemia.

50. (New) The method of claim 28, further comprising the steps of:

forecasting, based on the output data, heart filling intervals; and

identifying instances of comparable heart position for image collection based upon the heart filling intervals.

51.   (New) The method of claim 28, further comprising the step of:

determining patient respiratory cycles from baseline artifact undulations in the MP signals.

52.   (New) A multidimensional cardiac monitoring system (MCMS), comprising:

a plurality of physiological signal sensors positioned in geometrically distinct positions on a body relative to a heart, the sensors acquiring multidimensional physiologic MP signals from the heart;

a plurality of signal channels coupled to the sensors; and

a data processor coupled to the signal sensors that derives from the acquired MP signals output data representative of cardiac electrical activation events and including signal information not encompassed by any single signal channel.

53.   (New) The MCMS of claim 52, wherein the data processor extracts from the acquired MP signals undesirable electromagnetic signals attributable to local, distal or external signal sources.

54.   (New) The MCMS of claim 53, wherein each of the signal sensors is coupled to a one of the signal channels by a plurality of electrically conducting leads of similar trajectory not all of which are in electrical contact with the sensor, such that a common spurious signal is acquired in each lead attributable to signal sources external to the body.

55.   (New) The MCMS of claim 54, wherein each lead is twisted.

56.   (New) The MCMS of claim 52, wherein one or more of the signal channels contribute signals generated externally from the heart and providing information relative to the external signal sources.

57.   (New) The MCMS of claim 52, wherein the processor compares the acquired MP signals to stored data to determine which aspects of the MP signals are useful in generating the output data.

58.   (New) The MCMS of claim 57, wherein the processor compares signal differences from a plurality of sources to distinguish local, distal, global or external signal contributions based on different sensitivities relating to geometric position of sensors with respect to the heart.

59.   (New) The MCMS of claim 57, wherein said stored data represent electrocardiogram data obtained in the absence of the generation of one or more undesired signals or artifacts.

60.   (New) The MCMS of claim 59, wherein the one or more said undesired signals or artifacts include magneto effects that generate voltage or current from moving fluid in arteries or veins, signal artifacts from motion in a magnetic field or from magnetic field gradient effects, or artifacts from electric or magnetic effects on signals in leads.

61.   (New) The MCMS of claim 52, wherein the output data includes event indicator of a cardiac event, permitting medical equipment coupled to the MCMS to function as though connected to a patient with a reliable, threshold-detectable electrocardiogram.

62.   (New) The MCMS of claim 52, wherein the output data includes one or more variation indicators of a cardiac cycle variations, permitting prospective or

retrospective correction for variation in cardiac filling period by medical equipment coupled to the MCMS.

63. (New) The MCMS of claim 52, further comprising a pre-processor for eliminating undesired artifacts from and the editing of the acquired MP signals.

64. (New) The MCMS of claim 52, wherein the derivation performed by the processor further comprises:

comparing the MP signals to training data reflective of the expected temporal evolution of the MP signals to derive descriptive values reflective of desired signal features; and

fitting to the descriptive values feature template components determinative of output data information content to generate the output data.

65. (New) The MCMS of claim 52, wherein the output data includes a synthetic electrocardiogram waveform signal.

66. (New) The MCMS of claim 65, wherein a voltage offset of a continuous segment of the waveform signal permits identification of the presence of or changes in ischemia.

67. (New) The MSMS of claim 65, wherein a voltage offset of a segment of the waveform signal expressed as a series of voltage spikes of full or fractional height that count out segment deviation permits identification of the presence of or changes in ischemia.

68. (New) The MCMS of claim 52, wherein:

the acquired MP signals are electrocardiogram signals; and

the derived output data represents a respiratory cycle derived from baseline undulations in the acquired electrocardiogram signals.

69. (New) The MCMS of claim 52, wherein sensors of magnetic gradient switching are used as reference data to eliminate or isolate their undesirable contribution to the MP signals.

70. (New) The MCMS of claim 52,

wherein said coupling comprises a plurality of pairs of twisted electrically conductive leads, each pair being associated with a corresponding sensor, and a first lead of each pair being in electrical contact with a particular signal sensor and a second lead of each pair being electrically disconnected from said particular signal sensor but terminated adjacent thereto; and

further comprising a common mode rejector that eliminates from the acquired signal provided by the first lead undesired signals provided by the second lead.

71. (New) A physiological sensor coupler for spurious signal suppression, comprising:

a plurality of electrically conducting leads having a similar trajectory, fewer than all of which electrically couple to a physiologic sensor adjacent to a body, such that signals common to each lead in the plurality are reflective of spurious signals generated external to the body; and

means coupled to the plurality of leads for extracting the spurious signals from the signals acquired from the sensor.

72. (New) The coupler of claim 71, wherein the plurality of leads are twisted.

Appendix B (revised paragraph 4)

The ECG signal is commonly described in terms of a sequence of waves called P wave, QRS complex, and the T-wave (originally described by Willem Einthoven, *Einthoven W. Ueber die Form des menschlichen Electrocardiograms. Arch f d Ges Physiol 1895;60:101-123;* Nobel prize awarded 1924). The QRS complex may consist of just R wave or RS or qR or qS, where q, if present, is an initial down-going voltage deflection, R, if present, is the first up-going deflection ~~deflection~~ after the p-wave, and S, if present, is a subsequent down-going deflection (if there are further up-going and down-going waves in the QRS, those are labeled R', S', then R", S", respectively). The P-wave corresponds to electric activation of the small chambers of the heart. The R-wave or QRS complex corresponds to electrical activation of the large chambers of the heart. The T wave corresponds to the staggered end of electric charge redistribution recovery from the electrical activation of the large chambers.

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